From: Kirby, Sharon L [CC]
Sent: Tuesday, December 21, 2004 4:36 PM
To: NIEHS ICCVAM
Subject: Comments re November 3, 2004, Federal Register Notice Vol. 69, No. 212 pp. 64081-2

December 21, 2004

Dr. William Stokes, Director
NTP Interagency Center for the Evaluation of
  Alternative Toxicological Methods
National Institute of Environmental Health Sciences
Research Triangle Park, NC 27709
919-541-0947 (fax)
iccvam@niehs.nih.gov

Re: November 3, 2004, Federal Register Notice Vol. 69, No. 212 pp. 64081-2

Dear Dr. Stokes:

This letter is in response to a request for comments on Background Review Documents for four in vitro assays (HET-CAM, BCOP, ICE, and IRE) proposed for identifying potential ocular corrosives and severe irritants.

I am in favor of these well-established in vitro assays. Non-animal methods are preferred by a majority of Americans who, like me, would like to see elimination of animal tests whenever feasible and especially
for trivial items such as cosmetics and household products. Therefore, I
am pleased to have an opportunity to tell you why I believe alternative such as these should replace in vivo tests entirely.

Many experts agree that live animal tests actually do a better job of protecting manufacturers than consumers. The Draize test, for example, has been criticized by the scientific community since its development in
the 1940s. Dr. Stephen Kaufman of Bellevue Hospital noted that "[t]he Draize test is scientifically unsound and inapplicable to clinical situations. Reliance on this test is in fact dangerous, because the animal data cannot be reliably extrapolated to man. Substances 'proven'
safe in lab animals may in fact be dangerous to people."

ICCVAM's unbending demand for validation of the in vitro tests is somewhat difficult to understand or defend. Many of the available in

vitro alternatives to Draize clearly provide adequate information on ocular irritation. However, it is difficult to conduct an in vitro replacement validation study when the alternative is expected to favorably compare with in vivo results that are subjective and highly variable. I understand Draize testing can vary from lab to lab and even rabbit to rabbit! The Draize test should be abandoned and replaced with a new set of well-defined endpoints to which the proposed in vitro replacements can be compared. An entirely new approach is needed if validation is to be a valid objective.

Weakness exists in animal testing generally. In fact, many companies perform animal testing simply because their labs and personnel are already geared for them and their legal departments and insurance companies advise continuing to do it to shield the company from lawsuits. Even worse, armed with the "animal tested" defense, the very unreliability of many animal tests may provide manufacturers with an easy route to getting virtually any product on the market. People are rightly suspicious of companies that don't share their morality and conscience. Most consumers do not want animals to suffer because humans
want to use eye makeup, hair dye and shampoos.

Because of consumer demand in the U.S. and abroad, hundreds of cosmetics
and household-products companies no longer use animal testing and, instead, take advantage of a combination of methods to ensure safety such as maintaining extensive databases of ingredients and formula data and employing in vitro tests and human clinical studies. For example, Avon, which once killed about 24,000 animals annually testing its products, now uses the Irritation Assay System (Eytex and Skintex) along
with an in vitro test to assess irritancy levels.

In most cases, non-animal methods take less time to complete, cost less,
and are not plagued with issues of species differences. Corrositex, approved by the Department of Transportation as a substitute for the rabbit skin test, assesses corrosivity using a protein membrane designed
to function like skin and gives results in just a few hours for as little as $100 per test. TOPKAT, a software package used by the FDA, EPA and the U.S. Army, predicts oral toxicity and skin and eye irritation.

All the above seem sensible reasons for the ICCVAM to be more flexible in its evaluation of in vitro assays and more open to studying companies
like Tom's of Maine and researchers like Pharmagene Labs in England.

Consumers already know that in vitro tests are already being used safely
and effectively by industry today and government should also take this into consideration.

Continuing to support animal tests (even simply as confirmatory) will probably only result in impeding progress toward industry-wide adoption of cost-effective in vitro methods that really improve consumer safety. As you must know, the European Union's 7th amendment to the cosmetics Directive does not impose an immediate ban on animal testing and that may be the primary reason why the cosmetics industry did very little to develop and validate alternatives (between 1992 and 2003, the industry only tackled the two simplest animal tests to replace). In response to pressure from many animal protection groups, the Cosmetic, Toiletry and Fragrance Association has contributed $5 million since 1981 toward research into alternatives to Draize testing - a paltry figure compared to the annual advertising budget of even one of the association's member
companies.

I urge ICCVAM to take the lead in moving industry forward and a ban of all animal testing of cosmetic and consumer products would be just the incentive needed for serious research and development to end animal testing and make consumer products safer. As Dr. Coenraad F.M. Hendriksen of the Utrecht University, Netherlands, said: "Less animals make more science, and more science makes better regulations." Thank you for considering these comments.

Sincerely,

Sharon Kirby